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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,705	06/01/2001	William J. Roberts	1400-002	2502

7590

09/23/2003

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Phoenix, AZ 85018-2140

EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/23/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

The office action mailed on September 23, 2003 was returned to our office due to the forwarding time expired at the post office. Attached you will see a copy of the envelope that was returned to our office. Please file a change of address with our office so that future office actions can reach you.

Brenda L. Gray  
SLIE, TC 1600  
Team 4

# Office Action Summary

Application No.

09/872,705

Applicant(s)

ROBERTS, WILLIAM J.

Examiner

Sabiha Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 3-7, 11-13, 15-21, 29-33 and 38-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 8-10, 14, 22-28, 34-37 and 49-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 3-7, 11-13, 15-21, 29-33 and 38-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Presently claimed invention is drawn to a compound for supplementing the concentration of parent androgen as in claim 1.

Rejection under 102 (b) is withdrawn as applicant argues that steroid containing aloxymethylether is claimed which is not in the rejection. Claims 1-61 are pending. Claims 1, 2, 8-10, 14, 22-28, 34-37 and 49-61 were examined, as prodrug when hydrolyzed at 17-position would give the compounds indicated in the previous office action. Applicant is requested to clarify the invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 8-10, 14, 22-28, 34-37 and 49-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

1. Claim 1 is confusing. It is unclear what is the claimed invention. Citation of "compound comprising" in claims and claiming the compound is unclear. Is this a prodrug claim of composition, substrate, or use or the compounds?

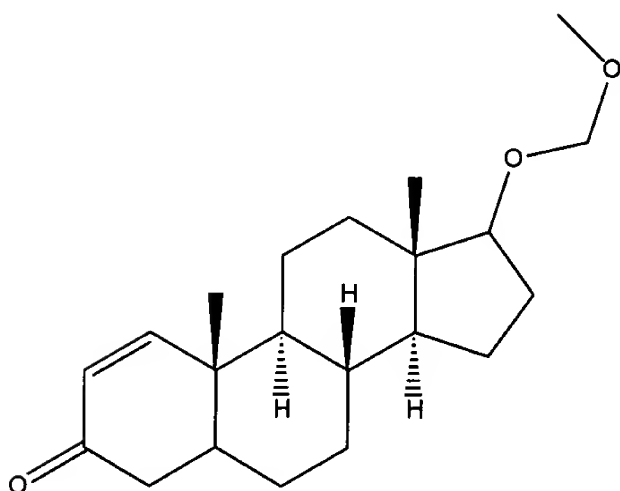
Compounds cannot comprise with certain groups. Compounds have certain structure. Applicants must write the claim particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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2. Compounds claimed in claims 16-21 does not contain alkoxymethyether at 17-position. Structures are drawn to make the difference clear. Therefore they are improperly dependent on claim 1.

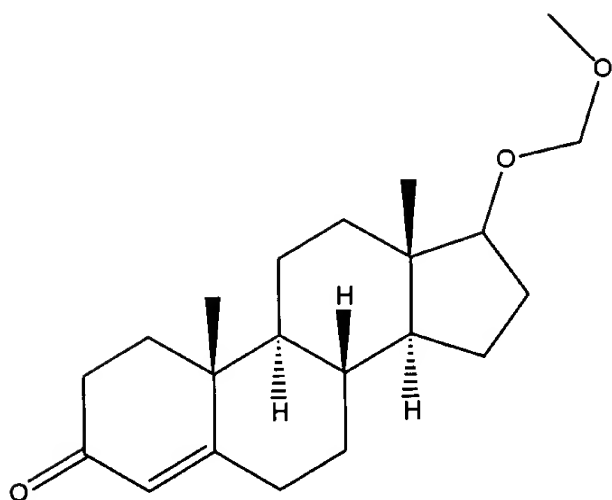
3. What is intended by a "promoiety comprising".

1. (Claim 13)



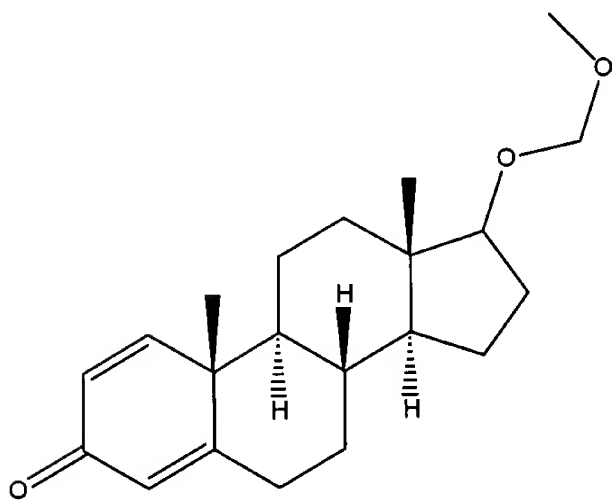
17-methoxymethoxyandrost-1-ene-3-one

2. (Claim 14)



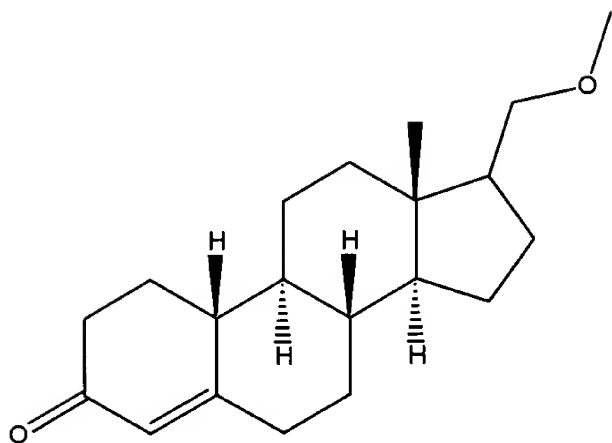
17-methoxymethoxyandrost-4-ene-3-one

3. (Claim 15)



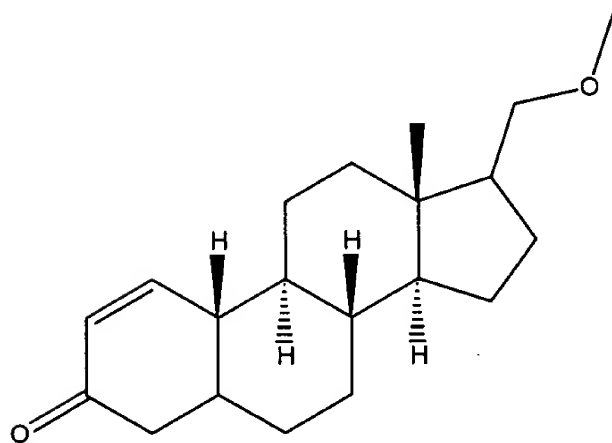
17-methoxymethoxyandrost-1,4-diene-3-one

4. (Claim 17)



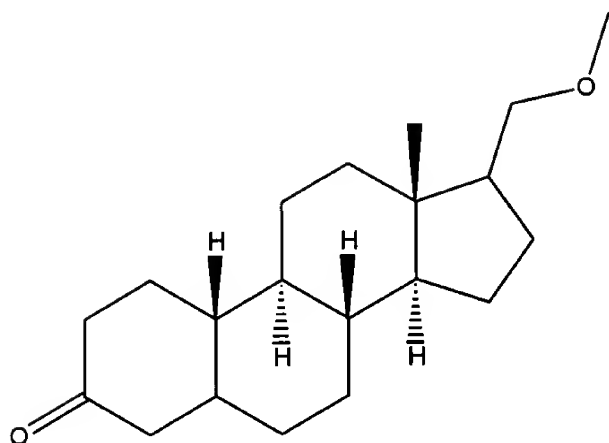
17-methoxymethylestra-4-ene-3-one

5. (Claim 16)



17-methoxymethylestra-1-ene-3-one

6. (Claim 21)



17-methoxymethylestran-3-one

No art rejection is being made at this point.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

SABIHA QAZI, PH.D  
PRIMARY EXAMINER